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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,093	Applicant(s) YORK ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54 - 82 is/are pending in the application.
- 4a) Of the above claim(s) 69, 76 - 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 54 - 68, 70 - 75 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-22-08</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Applicant is advised that the Examiner assigned to this Application has changed. The Examiner currently assigned to this Application is **Eric Silverman, PhD**, whose contact information can be found at the end of this action. Applicant is further advised that this Application is currently assigned to **Art Unit 1615**.

Receipt of amendment filed 11/16/2005 is acknowledged. Claims 32 - 53 were cancelled and claims 61 – 82 were added. Accordingly, claims 54 – 82 are pending.

Election/Restrictions

Newly submitted claims 69, 76 – 82 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original inventions are directed to generic methods of preparation or methods of preparing ketoprofen compositions. Accordingly, ketoprofen is deemed to be the species of active agent that was elected by original presentation, since originally elected claims all read on this species. Claims 76 – 82 are directed to methods where the active agent is paracetamol, which is deemed to be a separate species of the invention, since there is no evidence on the record which shows paracetamol and ketoprofen to be obvious variants. Claim 69 reads on a COX-2 selective inhibitor. Since there is no evidence on the record that shows ketoprofen to be a species or obvious variant of COX-2 inhibitors, claim 69 is also deemed to read on a distinct species. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 69, and 76 – 82 are withdrawn from consideration as being directed to a non-elected species of the invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

The objection to claims 52 and 53 is deemed moot since those claims have been cancelled.

Double Patenting

Claim 54 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/514,895, Pub. No. US 2005/0170000 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's argument has been fully considered, and is partially persuasive. Applicant's argument is deemed persuasive with respect to instant claim 60 to the extent that copending claim does not require a particular amount of the active substance to be present in an amorphous form. Applicant's argument is unpersuasive with respect to claim 54. Although copending claim does not delineate what materials are soluble in the solvent and anti-solvent, respectively, the artisan would understand from the commonly used meaning of the terms solvent and anti-solvent that the solubility should be as recited in instant claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 54 – 56 and 58 – 60 **remain** rejected under 35 U.S.C. 102(b) for reasons of record. In addition, new claims 61 – 68, 70 – 75 are rejected as being anticipated by the same prior art.

With regard to claims 61 – 65, these merely repeat limitations of claims 55, 56, 58 and 59, except that the parent dependent claim is claim 60. As claims 60, 55, 56, 58 and 59 were already properly rejected under this statute, over WO 95/01221 (Hanna 1), it follows that new claims 61 – 65 are also anticipated by Hanna 1. With regard to claims 66 – 74, the additional limitation in the generic claim that the particles be stable for at least 18 months is deemed inherent, since Hanna 1 teaches stable particles, and since there is nothing in Hanna to suggest that the particles degrade. Dependant claims 67 – 74 recite limitations of active agents, supercritical fluids, and excipients, all of which are disclosed by Hanna 1 as discussed in the previous office action. With regard to claim 74, the active substance disclosed by Hanna 1 is polar and the polymer is hydrophobic. With regard to claim 75, as Hanna 1 teaches the active substance to have a disturbance of crystallinity, it is deemed inherent that the active substance is completely in crystalline form.

Response to Arguments

Applicant's arguments have been fully considered, but are not persuasive. Applicant correctly argues that Hanna 1 discloses a method that causes the particles

Art Unit: 1615

produced thereby to demonstrate a disturbance of crystallinity. Applicant avers that, despite this teaching, the DSC/XRD data of the particles show that the particles which result from the method of Hanna 1 have considerable crystallinity. This argument is not persuasive with regard to claims 54 – 59 since these claims do not require the active substance to be in amorphous form. With regard to the other claims, Applicant's interpretation of the DSC/XRD data is deemed insufficient without evidence showing that this is a correct interpretation of the data. Applicant is invited to present evidence that the particles made by the method of Hanna 1 do not meet the crystallinity requirements of instant claims. Applicant may overcome this rejection by presenting sufficient evidence to this effect.

Applicant also argues that Hanna 1 is silent with regard to operating conditions regarding the solubilities of the different materials in different solvents. This is deemed to be an implicit teaching of Hanna 1. The artisan would understand the physics of solubility, and recognize that the active compound is soluble in one of the solvents and that the polymer is insoluble in this one of the solvents. Applicant uses the term "anti-solvent" to describe this solvent; though Hanna 1 may use different phraseology, the teaching is the same.

Claim Rejections - 35 USC § 103

Claims 54 – 60 **remain** rejected under 35 U.S.C. 103(a) for reasons of record.

Response to Arguments

Applicants arguments have been fully considered, but are not persuasive.

Applicant has argued against the references only individually. In response to applicant's

Art Unit: 1615

arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

No claims are allowed. Claims 69, and 76 – 82 are withdrawn from consideration. Claims 54 – 68, and 70 – 75 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571

Art Unit: 1615

272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

